

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION

IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION

MDL NO. 1968

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THIS DOCUMENT RELATES TO ALL CASES

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS  
COUNT FIVE OF  
THE MASTER CONSOLIDATED COMPLAINT FOR INDIVIDUALS

**I. INTRODUCTION**

This action arises out of Plaintiffs' various state and federal law claims against the Defendants relating to the manufacture and distribution of the prescription medicine Digitek®. Count Five, titled Negligence *Per Se*, is an attempt by Plaintiffs to recast a claim for alleged violations of the FDCA as a state tort claim. But Congress' intent is clear – “all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.” 21 U.S.C. 337(a). There is no private right of action for alleged violations of the FDCA. Because Plaintiffs' Count Five is an obvious attempt to bring a private cause of action for alleged violations of the FDCA, it should be dismissed.

**II. FACTS PERTINENT TO THIS MOTION TO DISMISS**

Plaintiffs filed the Master Complaint (ECF No. 73) on February 9, 2009. Count Five avers that Defendants “had an obligation not to *violate* the law” in the manufacture and

distribution of Digitek®. (Master Complaint, ¶90 (emphasis added).) Plaintiffs then allege that the Defendants “*violated* the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §301, *et seq.*, related amendments, codes and federal regulations provided thereunder . . . .” (Master Complaint, ¶91 (emphasis added).) More specifically, Plaintiffs claim that “Defendants’ acts constitute an adulteration and misbranding as defined by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. §331, and the regulations promulgated therefrom . . . .” and that “Defendants’ manufacturing, production, testing and inspection processes are not good manufacturing processes in *violation* of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §331, and the regulations promulgated therefrom . . . .” (Master Complaint, ¶¶93-94 (emphasis added).) Plaintiffs claim that these alleged violations of the FDCA support a claim for negligence *per se* because “[t]he acts and omissions set forth above, demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations . . . .” (Master Complaint, ¶95.)

### **III. LAW AND ARGUMENT**

#### **A. There is No Private Right of Action Under the FDCA.**

The FDCA consists of a set of laws providing the FDA with authority to oversee the safety and efficacy of food, drugs, and cosmetics. *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 160 (4th Cir. 1999); *see also Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (explaining that the FDCA is focused “on protecting the public interest in safety and efficacy”). The FDA will only approve a drug for sale once it is satisfied that the drug is both safe and effective. *Talley*, 179 F.3d at 160. To ensure safety and effectiveness, drugs are subject to rigorous testing before they are approved for sale. *Id.*

Congress, however, did not intend for the FDCA to create new private causes of action for violations of the Act. To resolve any doubt, the FDCA expressly limits enforcement of the Act to the federal government, stating, “all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States.” 21 U.S.C. § 337(a); *see also Merrell Dow Pharmaceuticals, Inc. v. Thompson*, 478 U.S. 804, 811 (1986) (holding that “Congress did not intend a private federal remedy for violations of the [FDCA] . . . .”); *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 349, fn. 4 (2001) (noting that the “[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit . . . .”); *Mylan*, 7 F.3d at 1139 (holding that a private litigant is “not empowered to enforce independently the FDCA”); *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (holding that “[c]onsidering the FDCA’s legislative history . . . ., we are compelled to conclude that Congress did not intend, either expressly or by implication, to create a private cause of action under the FDCA”).

**B. Plaintiffs’ Claim for Negligence *Per Se* Should be Dismissed as an Attempt to State a Private Cause of Action for Alleged Violations of the FDCA.**

Rule 12(b)(6) requires dismissal of a cause of action that fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). Although a trial court ruling on a Motion to Dismiss under Rule 12(b)(6) generally must “take the facts in the light most favorable to the plaintiff,” this Court “need not accept the legal conclusions drawn from the facts.” *Giarratano v. Johnson*, 521 F.3d 298, 302 (4th Cir. 2008) (quoting *Eastern Shore Mkts., Inc. v. J.D. Assocs. Ltd. P’ship*, 213 F.3d 175, 180 (4th Cir. 2000)). Unsupported conclusory statements are not

considered admitted for purposes of a motion to dismiss and are insufficient to withstand such a motion. *Eastern*, 213 F.3d at 180.

A cause of action for negligence *per se* is comprised of the same elements of a negligence claim, but the Court will “adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative requirement.” *Talley*, 179 F.3d at 158 (quoting Restatement (Second) of Torts § 286 (1965)). “The negligence *per se* doctrine, however, is not a magic transforming formula that automatically creates a private right of action for the civil enforcement, in tort law, of every statute.” *Id.* Instead, negligence *per se* has been considered a “moderate rule” that merely substitutes the legislature’s judgment for the Court’s judgment in instances where the legislature has set the standard of care. *Id.*

Enterprising plaintiffs, however, have attempted to use this state-law theory to bring a private right of action for violating the FDCA, even though such a claim is expressly prohibited. When presented with this very issue, the Third Circuit Court of Appeals explained how a theory of negligence *per se* should not be used to create a private right of action for violating the FDCA:

The theory of *per se* liability advanced by the plaintiffs here is quite different. Plaintiffs do not invoke the statutory violations to prove defendants’ liability for a separate underlying tort, but instead contend the violation themselves form a cause of action. This interpretation of *per se* liability would allow private plaintiffs to recover for violations of a federal statute that creates no private cause of action and, in fact, expressly restricts its enforcement to the federal government. (See 21 U.S.C.A. § 337(a) (West Supp. 1999). Plaintiffs’ theory would undermine section 337(a) by establishing a private, state-law cause of action for violations of the FDCA....

*In Re: Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 791 (3d Cir. 1999).

In other words, Plaintiffs should not be allowed to cloak an alleged violation of the FDCA in a state-law claim for negligence *per se* to circumvent Congress’ intent that there is no private cause

of action under the FDCA. *See* 21 U.S.C. § 337(a). “To allow a state *negligence per se* action based upon alleged violations of the FDCA would defeat the purpose of that prohibition.” *Talley v. Danek Medical, Inc.*, 7 F. Supp. 2d 725, 731, fn. 4 (E.D.Va. 1998).

Plaintiffs’ Count Five is an attempt to bring a private right of action for alleged violations of the FDCA. For example, Plaintiffs allege as the basis for Count Five that “Defendants *violated* the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, related amendments, codes and federal regulations provided thereunder . . . .” (Consolidated Complaint, ¶ 91 (emphasis added).) Plaintiffs further allege that “Defendants’ acts constitute an adulteration and misbranding as defined by the” FDCA. (Consolidated Complaint, ¶ 93). Moreover, Plaintiffs allege that “Defendants’ manufacturing, production, testing and inspection processes are not good manufacturing processes in *violation* of the” FDCA. (Consolidated Complaint, ¶ 94 (emphasis added).) After alleging each of these “violations” of the FDCA, Plaintiffs attempt to repackage their claim as negligence *per se* by making the conclusory statement that these violations “demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations, which were intended for the benefit of individuals such as Plaintiffs making Defendants negligent *per se*.” (Consolidated Complaint, ¶ 95). In accordance with the intent of Congress, as stated in the plain language of the FDCA (21 U.S.C. § 337(a)), this Court should dismiss Plaintiffs’ Count Five as an obvious attempt to enforce the FDCA by stating a private right of action for alleged violations of the Act.

#### IV. CONCLUSION

In sum, Plaintiffs' Count Five: Negligence *Per Se* should be dismissed because it is an attempt to allege a private cause of action for alleged violations of the FDCA, which is expressly prohibited by the plain language of the Act. *See* 21 U.S.C. § 337(a).

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**CERTIFICATE OF SERVICE**

I hereby certify that on April 20, 2009, I electronically filed the foregoing "Memorandum in Support of Motion to Dismiss Count Five: Negligence *Per Se* of the Master Consolidated Complaint for Individuals" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.



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